DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202211/S-004

SUPPLEMENT APPROVAL

Bayer HealthCare, LLC
Attention: Monica Hug
Regular Affairs, Regulatory Liaison
100 Bayer Boulevard, PO Box 915
Whippany, NJ 07981-0915

Dear Ms. Hug:

Please refer to your Supplemental New Drug Application (sNDA) dated September 10, 2015, received September 11, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oxytrol for Women (oxybutynin) Transdermal System, 3.9 mg.

This "Changes Being Effected" (CBE) sNDA provides for changes to the carton and Drug Facts label to insert the word "confusion" to follow "dizziness", as requested by the Agency in the August 13, 2015 supplement request letter. The proposed warnings section is now to read "Sleepiness, dizziness, confusion, and blurry vision may occur. Do not drive or operate machinery until you know how the patch affects you." The CBE sNDA also provides for a change in ownership from MSD Consumer Care, Inc. to Bayer HealthCare, LLC.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the 4-, 8-, and 14-count carton labels, the 14-count Club with backer card label and the consumer information leaflet submitted on September 10, 2015, and the 1-count immediate container label submitted on October 22, 2015, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 202211/S-004**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
03/03/2016